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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,921	12/04/2001	Keith D. Allen	R-714	7082
26619	7590	01/11/2005	EXAMINER	
DELTAGEN, INC.			SHUKLA, RAM R	
1031 Bing Street			ART UNIT	
San Carlos, CA 94070			PAPER NUMBER	

1632

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding..

Office Action Summary

Application No.

10/005,921

Applicant(s)

ALLEN ET AL.

Examiner

Ram R. Shukla

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-31, 33 and 35-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-31, 33 and 35-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/27/2004 has been entered.
2. Applicants' amendment and response filed 10/27/04 have been received and entered.
3. Claim 32 and 34 has been cancelled.
4. New claims 35-40 have been entered.
5. Claims 28-31, 33 and 35-40 are pending and under consideration.

Claim Objections

6. Claim 31 is objected to because of the following informalities: Step d of the claimed method ends with "transgenic". It is missing "mouse". Appropriate correction is required.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 28-34 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for reasons of record set forth in the previous office action of 12/03/03 and 7/28/04.

Claims 38-34 also remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility

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or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention for reasons of record set forth in the previous office action of 12/03/03 and 7/28/04.

It is noted that applicants cancelled claims 32 and 34 and added new claims 35-40. New claim 35 is drawn to a transgenic mouse with a genome comprising a null endogenous CASH allele. Claims 36-40 further limit the mouse to a heterozygous mouse, a homozygous mouse, and limit the exogenous DNA comprised into the genome of the transgenic mouse. The newly presented claims remain rejected for reasons of record because while they encompass the same invention.

Response to Arguments

Applicant's arguments filed 10/27/04 have been fully considered but they are not persuasive. Applicants have cited Patent Office's Utility guidelines and MPEP and have argued:

(emphasis added)(MPEP § 2107, II (A)(3); II (B)(1)). Thus, according to Patent Office guidelines, a rejection for lack of utility may not be imposed where an invention has a well-established utility or is useful for any particular practical purpose. The present invention satisfies either standard.

However, applicants have discussed only part of the guidelines and that too out of the context. First, applicants did not provide any evidence of substance to support their arguments. Second, applicants ignored rest of the MPEP Utility guidelines, particularly MPEP 2707.01 (R1) I, which explains what is a specific utility and a substantial utility. Under the subheading of Specific Utility, MPEP states:

A "specific utility" is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention. Office personnel should distinguish between situations where an applicant has disclosed a specific use for or application of the invention and situations where the applicant merely indicates that the invention may prove useful without identifying with specificity why it is considered useful.

While applicants argue that knockout mouse are generally useful and cite some NIH document. While the context of the cited part of the unnamed NIH document cannot be determined because applicants did not provide a copy of the document, the cited NIH document does not

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provide any evidence to support that the transgenic mouse claimed in the instant applicants has a utility since no specific utility has been described. Applicants are reminded that the MPEP does not recognize a general utility of a broad class of invention as a specific utility of a claimed invention. Applicants' arguments on pages 2-4 of the response that include discussion of the text books *Genes VII* or *Molecular Biology of the Cell* are irrelevant as is the comment from NIH because they do not address the utility of a particular mouse claimed instantly. Regarding applicants' arguments that knockout mice are research tools, it is noted that applicants did not state research tool for what? Further characterizing the function of a gene, but that is not a specific and substantial utility.

Next, applicants argue that commercial use of the claimed transgenic mouse has been established because the transgenic mouse has been ordered by one institution. However, these arguments are not persuasive because this asserted sale does not provide support for specific utility because, first applicants did not state what was the utility for which alleged institution was ordering the claimed transgenic mouse and second, there is no evidence that such a utility for the mouse was describe in the specification. Therefore, applicants' arguments fail to establish a specific and substantial utility for the claimed transgenic mouse.

Next applicants argue that the issue in the instant case is similar to that in *In re Brana*. However, applicants' arguments are misplaced since in the *In re Brana*, the compounds were disclosed to be effective as anti-tumor agents, but in the instant case, applicants have not provided what will be the utility of the claimed transgenic mouse. Therefore, analysis in *In re Brana* is not applicable to the instant case. While applicants have discussed the *In re Brana*, they have not discussed as to how the case compared to the instant application. Patent Office has met its burden of providing evidence why the instantly claimed invention lacked a specific and substantial utility (see pages 3-6 of the office action of 12/3/03). Applicants' arguments that definite proof that the phenotypes observed in the null mouse would be the same as in humans in not a prerequisite are misplaced since the issue is not of definitive proof, rather the issue is of any correlation of the CASH gene with any disease and there is no evidence of record to indicate that. Additionally, because pain and seizure are symptoms that occur in several gene disruptions or non-gene disruption conditions, these phenotypes cannot reliably contribute to disruption in CASH gene. Applicants' entire line of argument has been a general utility for any knockout mouse which is misplaced and incorrect since utility analysis is for a particular claimed

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invention, in the instant case a knockout mouse comprising disruption of endogenous CASH gene. The applicants have not provided any substantial evidence to obviate the grounds of rejection set forth in the previous office actions or this office action and that CASH gene is associated with any disease or condition or that seizure or pain or other phenotype as claimed or disclosed is specific to CASH gene disruption. It is emphasized that contrary to the arguments of the applicants, the utility to make null reporter alleles or knockout transgenic mouse is general is not the issue here, rather the issue is the utility of a CASH gene null transgenic mouse.

The utility and enablement rejections of record are therefore maintained.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 is indefinite because it recites the limitation "the target gene" in line 6 of step c of the claimed method. There is insufficient antecedent basis for this limitation in the claim.

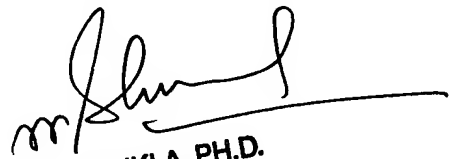
12. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (571) 272-0735. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for TC 1600 is (571) 273-8300. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Dianiece Jacobs whose telephone number is (571) 272-0532.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632



RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER